Neon Therapeutics Logo

# Neon Therapeutics Announces New Strategic Focus on Novel T Cell Programs

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*Lead program, NEO-PTC-01, is a personalized neoantigen adoptive T cell therapy candidate to address refractory solid tumors*

*Corporate restructuring effected to focus resources while exploring strategic options*

CAMBRIDGE, Mass., Nov. 20, 2019 (GLOBE NEWSWIRE) -- Neon Therapeutics, Inc. (Nasdaq: NTGN) today announced its new strategic focus on the development of its novel neoantigen-based T cell programs, in conjunction with a corporate restructuring. Neon will focus its efforts on the advancement of both personal and precision neoantigen-targeted T cell therapy candidates. Neon's most advanced program is NEO-PTC-01, its personal neoantigen-targeted T cell therapy candidate consisting of multiple T cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor. Neon expects to file a Clinical Trial Application (CTA) in Europe by the end of 2019 to evaluate NEO-PTC-01 in patients with metastatic melanoma who are refractory to checkpoint inhibitors.

"Prioritizing development of novel T cell therapies will leverage our years of expertise and learnings in pioneering neoantigen science, while positioning Neon to best deliver new therapies that could potentially improve patient outcomes and bring value to shareholders. The strategic restructuring will enable us to focus resources to execute on this vision. We acknowledge this decision impacts many talented employees who helped build Neon into a leader in neoantigen-based-therapies and we are grateful for their many contributions," said Hugh O'Dowd, Neon's Chief Executive Officer.

NEO-PTC-01 leverages Neon's neoantigen platforms, including RECON®, its machine-learning bioinformatics platform, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T cells *ex vivo.* Neon believes that this approach will allow NEO-PTC-01, a non-engineered product that leverages peripheral blood mononuclear cells (PBMCs) as starting material, to specifically target each patient's individual tumor with T cells that can drive a robust and persistent anti-tumor response.

The initial clinical development of NEO-PTC-01 will be focused on demonstrating monotherapy activity targeting metastatic solid tumors that are refractory to checkpoint inhibitor therapy. Following the planned submission of a CTA by the end of 2019, the company plans to initiate a Phase 1 dose escalation clinical trial in second-line metastatic melanoma in collaboration with the Netherlands Cancer Institute. The second planned indication for NEO-PTC-01 is second-line metastatic ovarian cancer, with potential to expand to other solid tumor types and potential development in the United States.

"NEO-PTC-01 has the potential to unlock the potency of cell therapy in solid tumors with several key advantages that overcome the challenges of other cell therapy approaches. In pre-clinical development and in several patient samples, we have demonstrated the ability to produce multiple enriched neoantigen-specific $CD8^+$ and $CD4^+$ T cell populations, including both memory and *de novo* T cell responses, that killed patient-specific tumors by targeting their tumor neoantigens. We believe that neoantigen targets will provide the tumor specificity required to develop safe, effective and durable T cell therapies for the treatment of solid tumors," said Richard Gaynor, M.D., Neon's President of Research and Development.

Neon is also advancing a precision T cell therapy program targeting shared neoantigens in genetically defined patient populations. This process utilizes off-the-shelf targets with a patient's own PBMCs to develop a novel cell-based immunotherapy enabling rapid deployment for each patient. The lead program from this approach, NEO-STC-01, is a T cell therapy candidate targeting shared RAS neoantigens initially in pancreatic cancer and is currently in preclinical development.

**Corporate Restructuring**

As part of this new strategic focus, Neon is reducing its workforce by approximately 24% of its current headcount. At this time, Neon will cease undertaking new additional spending commitments related to its cancer vaccine programs, NEO-PV-01 and NEO-SV-01. The company will continue to conduct follow-up from its NT-002 clinical trial of NEO-PV-01 in first-line patients with untreated advanced or metastatic non-small cell lung cancer, with plans to report clinical data from this trial in the third quarter of 2020. Neon also plans to cease future enrollment in its NT-003 trial in metastatic melanoma. Neon believes these actions will improve its potential to bring value to patients, employees and shareholders. As part of these cost reduction efforts, Neon intends to explore strategic options.

Neon expects that the restructuring and other cost-saving efforts will result in approximately $35 million in annualized cost savings. Neon estimates that it will incur approximately $1.5 million of pre-tax charges for severance and other costs related to the restructuring in 2019. With this restructuring, Neon now expects that its cash, cash equivalents and marketable securities will enable it to fund its operating expenses and capital expenditure requirements into the third quarter of 2020.

There can be no assurance that Neon's restructuring and other cost-saving efforts will be sufficient to continue the development of NEO-PTC-01 or its other programs through completion of the planned or ongoing clinical trials, nor that Neon's exploration of strategic alternatives will result in any transaction being entered into or consummated. Neon has not set a timetable for completion of this strategic review process and Neon does not intend to comment further unless or until its board of directors has approved a definitive course of action, the review process is concluded, or it determines that disclosure is required or appropriate.

**About Neon Therapeutics**

Neon Therapeutics is a biotechnology company developing novel neoantigen-targeted T cell therapies, dedicated to transforming the treatment of cancer by directing the immune system towards neoantigens. Neon is using its neoantigen platform to develop both personal and precision neoantigen-targeted T cell therapy candidates. Neon's most advanced program is NEO-PTC-01, its personal neoantigen-targeted T cell therapy candidate consisting of multiple T cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor. Neon expects to file a Clinical Trial Application (CTA) in Europe by the end of 2019 to evaluate NEO-PTC-01 in patients with metastatic melanoma who are refractory to checkpoint inhibitors.

For more information, please visit neontherapeutics.com.

**Forward-Looking Statements**

This press release contains “forward-looking statements” of Neon Therapeutics, Inc. within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, express or implied statements regarding our ability to obtain and maintain regulatory approval of our product candidates; the potential timing and advancement of our clinical trials; the potential timing and manner of data readouts from our ongoing and planned clinical trials; the design and potential efficacy of our therapeutic approaches; our plans to explore strategic alternatives; financial plans and projections, including its restructuring and other cost-saving efforts and impact on cash runway; and our ability to replicate results achieved in our preclinical studies or clinical trials in any future studies or trials. Any forward-looking statements in this press release are based on management’s current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: uncertainties related to the initiation, timing and conduct of studies and other development requirements for our product candidates; the risk that any one or more of our product candidates will not be successfully developed and commercialized; the risk that the results of preclinical studies and clinical trials may not be predictive of future results in connection with future studies or trials; the risk that Neon’s collaborations will not continue or will not be successful; risks related to our ability to protect and maintain our intellectual property position; risks related to our capital requirements, use of capital and unexpected expenditures, including our ability to manage operating expenses or obtain funding to support planned business activities or to explore and establish strategic alternative transactions; risks related to our ability to attract and retain personnel; and risks related to the ability of our licensors to protect and maintain their intellectual property position. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Neon’s actual results to differ from those contained in the forward-looking statements, see the section entitled “Risk Factors” in Neon’s most recent Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Neon’s other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Neon undertakes no duty to update this information unless required by law.

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